House of Representatives

General Assembly

File No. 622

January Session, 2009

House Bill No. 6379

House of Representatives, April 15, 2009

The Committee on Appropriations reported through REP. GERAGOSIAN of the 25th Dist., Chairperson of the Committee on the part of the House, that the bill ought to pass.

AN ACT IMPLEMENTING THE GOVERNOR'S BUDGET RECOMMENDATIONS CONCERNING MAXIMIZATION OF PHARMACY REBATES.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. Subsection (e) of section 17b-491 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(e) **[**The commissioner shall establish an application form whereby a pharmaceutical manufacturer may apply to participate in the program. Upon receipt of a completed application, the department shall issue a certificate of participation to the manufacturer.**]** Participation by a pharmaceutical manufacturer shall require that the department shall receive a rebate from the pharmaceutical manufacturer for prescriptions covered under the program and for prescriptions covered by the department pursuant to subsection (c) of section 17b-265e, as amended by this act. Rebate amounts for brand name prescription drugs shall be equal to those under the Medicaid

program. Rebate amounts for generic prescription drugs shall be established by the commissioner, provided such amounts may not be less than those under the Medicaid program. A participating pharmaceutical manufacturer shall make quarterly rebate payments to the department for the total number of dosage units of each form and strength of a prescription drug which the department reports as reimbursed to providers of prescription drugs, provided such payments shall not be due until thirty days following the manufacturer's receipt of utilization data from the department including the number of dosage units reimbursed to providers of prescription drugs during the quarter for which payment is due. The department may enter into contracts for supplemental rebates for drugs that are on a preferred drug list or formulary established by the department.

Sec. 2. Subsection (c) of section 17b-265e of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

(c) The Department of Social Services shall, in accordance with the provisions of this section, pay claims for prescription drugs for Medicare Part D beneficiaries, who are also either Medicaid or ConnPACE recipients and who are denied coverage by the Medicare Part D plan in which such beneficiary is enrolled because a prescribed drug is not on the formulary utilized by such Medicare Part D plan. Payment shall initially be made by the department for a thirty-day supply, subject to any applicable copayment. The beneficiary shall appoint the commissioner as such beneficiary's representative for the purpose of appealing any denial of Medicare Part D benefits and for any other purpose allowed under federal law and deemed necessary by the commissioner. Pharmaceutical manufacturers shall pay rebate amounts **[**established pursuant to section 17b-491**]** to the department for prescriptions paid by the department pursuant to this section on or after January 1, 2007. **[**The beneficiary shall appoint the commissioner as such beneficiary's representative for the purpose of appealing any denial of Medicare Part D benefits and for any other purpose allowed

under said act and deemed necessary by the commissioner.**]** For ConnPACE recipients, unit rebate amounts shall be equal to unit rebate amounts paid under the Medicaid program. For recipients of both Medicaid and Medicare, the unit rebate amount shall be calculated as follows: (1) For noninnovator multiple source drugs, the average manufacturer's price multiplied by eleven per cent; and (2) for single source or innovator drugs, the greater of the average manufacturer's price multiplied by fifteen and one tenth per cent or the average manufacturer's price minus best price. In the event the calculated rebate would establish a new Medicaid best price, the unit rebate amount will be capped at the average manufacturer's price minus best price. A manufacturer shall not be required to provide a rebate for a prescription drug that is new to the marketplace until the quarter in which the manufacturer has established a Medicaid best price for the product. The department may enter into contracts for supplemental rebates for drugs that are on a preferred drug list or formulary established by the department.

Sec. 3. Section 17b-491c of the general statutes is repealed and the following is substituted in lieu thereof (*Effective from passage*):

[Except as provided in subsection (c) of section 17b-265e,**]** (a) On and after February 1, 2008, any pharmaceutical manufacturer of a prescription drug covered by the Department of Social Services under **[**any of the**]** a state medical assistance **[**programs**]** program administered by the department that is a federally qualified state pharmacy assistance program shall provide rebates to the department for prescription drugs paid for by the department **[**on or after February 1, 2008. The amount of rebates and the administration of the program shall be in accordance with subsections (e) and (f) of section 17b-491**]** under such program in unit rebate amounts equal to the unit rebate amounts paid under the Medicaid program.

(b) On and after February 1, 2008, any pharmaceutical manufacturer of a prescription drug covered by the department under a state medical assistance program that is not a federally qualified state

pharmacy assistance program shall provide rebates to the department. The unit rebate amount shall be calculated as follows: (1) For noninnovator multiple source drugs, the average manufacturer's price multiplied by eleven per cent, and (2) for single source or innovator drugs, the greater of the average manufacturer's price multiplied by fifteen and one tenth per cent or the average manufacturer's price minus best price. In the event the calculated rebate would establish a new Medicaid best price, the unit rebate amount will be capped at the average manufacturer's price minus best price.

(c) The department may enter into contracts for supplemental rebates for drugs that are on a preferred drug list or formulary established by the department.

(d) Pharmaceutical manufacturers shall submit written confirmation of participation on a form prescribed by the Commissioner of Social Services, that states the terms of participation, including, but not limited to, the process by which a manufacturer may discontinue participation. The department shall provide advance notice to participating manufacturers if a new pharmacy assistance program is established and shall provide the manufacturers with the opportunity to discontinue participation. The department shall promptly notify participating manufacturers if a state pharmacy assistance program becomes disqualified. If a program becomes disqualified and a manufacturer has paid rebates at the rate for a qualified program, the department shall reimburse the manufacturer the amount overpaid as a result of disqualification.

(e) A manufacturer shall not be required to provide a rebate for a prescription drug that is new to the marketplace until the quarter in which the manufacturer has established a Medicaid best price for the product.

(f) No payment shall be made by the department for the prescription drugs of a manufacturer that does not provide rebates to the department pursuant to this section unless a specific drug is determined by the department to be medically necessary for an

individual client.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*from passage*	17b-491(e)
Sec. 2	*from passage*	17b-265e(c)
Sec. 3	*from passage*	17b-491c

HS *Joint Favorable C/R* APP

APP *Joint Favorable*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either House thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 09 $	FY 10 $
Department of Social Services	GF - Cost Avoidance	6,200,000	2,900,000

Municipal Impact: None

Explanation

This bill clarifies current practice by specifically allowing the Department of Social Services (DSS) to enter into contracts for supplemental pharmacy rebates. Pharmaceutical rebates are used to offset costs under the Medicaid, ConnPACE, State Administered General Assistance, Charter Oak, and HUSKY programs and the Medicare Part D Supplemental Needs Fund. It is estimated that without the specific language under this bill, DSS would lose $6.2 million in rebates in FY 09, $2.9 million in FY 10 and $2 million in FY 11. As the rebates are used to offset appropriations, these losses would necessitate higher appropriations to meet current programmatic projections.

The Out Years

The FY 11 impact identified above would continue into the future subject to inflation and caseload changes.

Sources: Department of Social Services Caseload Information

OLR Bill Analysis

HB 6379

AN ACT IMPLEMENTING THE GOVERNOR'S BUDGET RECOMMENDATIONS CONCERNING MAXIMIZATION OF PHARMACY REBATES.

SUMMARY:

Federal Medicaid law establishes two different formulas for calculating drug rebates for drugs dispensed to Medicaid recipients—one for single source innovator (brand-name) drugs and another for noninnovator multiple source drugs (generics). Retroactive to February 1, 2008, this bill requires the rebates the Department of Social Services (DSS) collects from drug manufacturers whose products are provided to Connecticut Pharmaceutical Contract to the Elderly and Disabled (ConnPACE) and State-Administered General Assistance (SAGA) recipients to equal the rebates it collects for Medicaid recipients. For the other DSS pharmacy assistance programs, the bill establishes a lower rebate for innovator and single source drugs.

The bill also:

1. prohibits DSS from paying for any prescription drugs of manufacturers that do not provide rebates unless DSS has determined that a particular manufacturer's drug is medically necessary for one of DSS' clients;

2. specifies that drug manufacturers must provide rebates only after their drug has been on the market for a certain period of time;

3. requires participating manufacturers to notify DSS when they are providing rebates, on a form DSS prescribes, and requires DSS to provide notice to them when it establishes a new

pharmacy assistance program;

4. removes a requirement that DSS have an application form and issue certificates for every manufacturer providing rebates; and

5. permits DSS to enter into additional contracts for supplemental rebates for drugs on its preferred drug list.

EFFECTIVE DATE: Upon passage

DRUG REBATES IN DSS PROGRAMS

General Rebate Requirement

The bill provides that retroactive to February 1, 2008, any manufacturer of a drug covered by DSS medical assistance programs that are "federally qualified" state pharmacy assistance programs (SPAP) must provide rebates to DSS. These rebates must be the same as those DSS receives for Medicaid-covered drugs.

Under federal law, for noninnovator multiple source drugs, the Medicaid rebate the state receives equals the average manufacturer's price (AMP) times 11%. For single source or innovator drugs, the rebate is the greater of the AMP times 15.1% or the AMP minus best price (BP). In addition, the state receives an additional rebate when the price of the drug increases faster than inflation (see BACKGROUND).

For non-federally qualified programs, and also retroactive to February 1, 2008, the bill establishes a separate formula for single source or innovator drugs. (For both federally and non-federally qualified programs, the rebates for noninnovator multiple source drugs remain the same.) It is the Medicaid formula without the additional rebate for inflation. But if the rebate would establish a new Medicaid BP, the unit amount is capped at the AMP minus BP.

Current law requires drug manufacturers to provide rebates for drugs covered by any DSS medical assistance program, and the amount and administration of the rebates are calculated in accordance with the rebates negotiated under the ConnPACE program.

The bill specifies that a manufacturer is not required to provide a rebate for a drug that is new to the market until the quarter in which the manufacturer has established a Medicaid BP for it.

The bill does not define what a federally qualified program is (see BACKGROUND).

ConnPACE

The bill requires the unit rebate amount for drugs dispensed under the ConnPACE program to be the same as it is under the Medicaid program.

The bill eliminates a requirement that the DSS commissioner establish an application form for manufacturers who want to participate in the ConnPACE program, as well as a requirement that DSS issue a certificate of participation for manufacturers whose drugs are purchased under that program.

Dually Eligible for Whom Supplemental Needs Fund Pays for Prescriptions

In general, the state does not collect rebates for individuals eligible for both Medicare and Medicaid since the Medicare Part D program pays for their drugs and that program negotiates directly with the drug companies. But for drugs that the Part D plans do not cover, the state has used a special fund (Supplemental Needs Fund) to pay for them. Under the bill, for noninnovator multiple source drugs, the rebate for these drugs equals the average manufacturer's price (AMP) times 11%. For single source or innovator drugs, the rebate is the greater of the AMP times 15.1% or the AMP minus BP.

The bill provides that if the calculated rebate establishes a new Medicaid BP, the unit rebate amount will be capped at the AMP minus BP.

The bill specifies that a manufacturer is not required to provide a rebate for a drug that is new to the market until the quarter in which the manufacturer has established a Medicaid BP for it.

Administration of Rebates

The bill requires manufacturers to submit written confirmation of participation on a form that DSS prescribes stating the terms of participation, including the process for discontinuing participation.

If DSS establishes a new pharmacy assistance program, the bill requires it to provide (1) advance notice to already participating manufacturers and (2) opportunity for them to stop participating.

The bill likewise requires DSS to promptly notify participating manufacturers if they become disqualified. If disqualification occurs and a manufacturer has paid rebates at the rate for a qualified program, DSS must reimburse the manufacturer the amount it overpaid as a result of the disqualification.

Supplemental Rebates for Drugs on Preferred Drug List (PDL)

The bill permits DSS to enter into contracts for supplemental rebates for drugs that are on its PDL or a formulary that it establishes. By law, DSS can negotiate supplemental rebates for Medicaid-covered drugs on its PDL.

BACKGROUND

Medicaid Rebates—Federal Law

Since 1990, federal law has required drug manufacturers to enter into rebate agreements with state Medicaid programs and requires these programs to cover any of those manufacturer's drugs. States share any rebates collected with the federal government, since it pays a share of the states' drug expenditures (50% in Connecticut).

The federal law defines "best price" with respect to a single source or innovator multiple source drug as the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, HMO, nonprofit entity, or government entity within the United States Best price (1) includes cash discounts, free goods contingent on any purchase requirement, volume discounts, and rebates; (2) must be determined without regard to special packaging,

labeling, or identifiers on the dosage form or product or package; and (3) may not take into account merely nominal prices.

The law also provides that for any covered outpatient drug that the Food and Drug Administration approves, the rebate must be provided during the first full calendar quarter after the day on which the drug is first marketed (42 USC §1986r-8).

Current DSS Rebates

DSS presently collects rebates on all drugs covered under the Medicaid program, which includes HUSKY A. It also receives supplemental rebates for Medicaid-covered drugs on its preferred drug list.

DSS also collects regular rebates from manufacturers that participate in ConnPACE, as well as the Connecticut AIDS Drug Assistance Program. (The latter rebates go to the Department of Public Health.)

For the state-funded, SAGA medical assistance program, DSS collects minimal rebates, in part because until recently, SAGA care was managed and the health centers were expected to negotiate the rebates directly.

Although it has the legal authority, DSS does not collect rebates under either the HUSKY B or Charter Oak Health Plan. Likewise, DSS is not collecting drug rebates for drugs (1) provided to Medicaid recipients who are also eligible for Medicare and (2) for which DSS pays because they are not covered by the recipient's Medicare Part D plan. Apparently, the manufacturers are requesting individual contracts to do so, based on their interpretation of the state ConnPACE law (that the bill repeals).

Federally Qualified SPAPs

According to the federal Centers for Medicare and Medicaid Services (CMS), a SPAP is a pharmacy assistance program developed specifically for the aged, indigent, low-income elderly, or other

financially vulnerable people. In Connecticut, besides Medicaid, this would include ConnPACE, but not the Connecticut AIDS Drug Assistance Program, HUSKY B, the Charter Oak Health Plan, or the Supplemental Needs-funded program that provides drug coverage to dually eligible individuals whose Medicare Part D plan formulary does not include particular prescribed drugs.

CMS has told the state that it cannot collect the Medicaid rebate for programs that are not federally qualified SPAPs, because to do so would set a new best price and force manufacturers to set a lower Medicaid rebate.

COMMITTEE ACTION

Human Services Committee

Joint Favorable Change of Reference
Yea 18 Nay 0 (03/12/2009)

Appropriations Committee

Joint Favorable
Yea 49 Nay 0 (03/27/2009)